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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,819	12/27/2001	Allan Tanghoj	P67397US0	2805

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EXAMINER

GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/026,819	Applicant(s) TANGHOJ ET AL.	
	Examiner Andrew M. Gilbert	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 29-73 is/are pending in the application.

4a) Of the above claim(s) 2, 5-6, 8-15, 17-20, 24-25, 30-31, 35-40, 42-59, 61, 65, 66, and 73 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 7, 16, 21-23, 26-27, 29, 32-34, 41, 60, 62-64, 67, 68, 70-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/05/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/05/2005 has been entered.

Acknowledgements

2. By amendment filed on 12/05/2005 the Applicant has cancelled claims 74-79 and amended claims 19, 54, and 60. Claims 1-27 and 29-73 are pending in this application. Claims 1 and 60 are independent. Claims 61, 65, 66, and 73 are withdrawn from further consideration.

3. Claims 2, 5-6, 8-15, 17-20, 24-25, 30-31, 35-40, 42-59 are dependent on generic claim 1 have been withdrawn as being drawn to a nonelected species, there being no allowable generic or linking claim, since claim 1 is found not allowable as previously stated in the office action filed 6/6/2005.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 12/05/2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the catheter outlet adapted to dismantle the proximal end of the catheter from the catheter package must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3, 4, 7, 16-20, 29, 33, 34, 60, 69, 71, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Osborne et al (5041085). In reference to independent claims 1 and 60, Osborne et al discloses a catheter assembly (101) allowing for non contaminated insertion of the catheter into a urinary canal (col 1, Ins 25-34), said assembly comprising a urinary catheter defining a conduit (104; 107) and having a proximal end adapted for insertion into a urinary canal of an individual and an opposite distal end (col 1, Ins 25-34; Fig 2); a catheter package (110) having a hose (Fig 1) with a cavity (113) for accommodation of the catheter and, in a proximal end thereof, a catheter outlet (111) adapted to dismantle the proximal end of the catheter from the catheter package, said package also being provided with an opening (124) separate from said catheter outlet for draining a liquid substance out of the package, said opening being closed by a closing structure (106) connected to said urinary catheter for causing opening of the package upon removal of the catheter from the package prior to use (col 5, Ins 1-10); and a sealing structure (118; Fig 1) adapted to provide a substantially liquid tight seal between the catheter package and the urinary catheter (Fig 1; col 4, Ins 23-48), while the catheter is being dismantled.

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8. In reference to claims 3-4, 7, 16-20, 29, 33, 34, 69, 71, and 72 Osborne et al additionally discloses the sealing structure is arranged between an outer surface of the urinary catheter and an inner surface of the hose (Fig 1), the cavity (113) thereby defining an upper receptacle (around 127) located near the proximal end of the package and an oppositely located lower receptacle (113) between the catheter and the hose; the sealing structure includes a radially outwardly extending protrusion (106; Fig 1) of the outer surface of the catheter; wherein at least one protrusion defines a resilient vane (106; Fig 1) adapted to contact an inner surface of the hose (112); a distance from the proximal end of the catheter package to the position of the sealing structure constitutes between 0 and 100 % of a total distance between the proximal end of the catheter package and the opposite distal end of the package (Fig 1); wherein the sealing structure is adapted to provide a substantially liquid tight seal between the catheter package and the catheter, while a first length of the catheter is being dismantled over a first dismantle period (Fig 1; col 4, lns 23-48); a flow channel (107) is defined between the catheter while the catheter is being dismantled over a second dismantle period (Fig 1; col 4, lns 23-48); a length of the first dismantle period constitutes between 0 and 100 % of a total length of the package (Fig 1; col 4, lns 23-48); the substantially liquid tight seal is provided continuously between the catheter package and the catheter over the first dismantle period (Fig 1; col 4, lns 23-48); the opening is provided in the distal end of the package (124; Fig 1); wherein the outlet and the flow channel are provided so as, in a second position of the closing structure in relation to the outlet, to allow a liquid substance to flow from the conduit of the catheter and out of the package (Fig 1; col 4,

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Ins 23-48; col 5, Ins 1-10); the flow channel of the closing structure further includes at least one inlet (109; 106; 124) allowing a liquid substance to flow between the one of either the lower or upper receptacles and the conduit of the catheter.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 21-23, 26-27, 41, 62-64, and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne et al in view of Hursman et al (6004305). Osborne et al discloses the invention substantially as claimed except for a friction-reducing substance; the package having a liquid tight wetting pocket; an amount of the substance sufficient for effecting a treatment of at least the proximal end of the catheter; the substance is a lubricant being a water based treatment solution for a hydrophilic catheter; and the package is being closed in the proximal end by a detachable closure. Hursman et al teaches that it is known to have a friction-reducing substance (col 1, Ins 50-51); the package having a liquid tight wetting pocket (20); an amount of the substance sufficient for effecting a treatment of at least the proximal end of the catheter (col 1, Ins 50-60); the substance is a lubricant being a water based treatment solution for a hydrophilic catheter (col 2, Ins 59-66); and the package is being closed in the proximal end by a detachable closure (60; Fig 3) for the purpose of improved operability and ease of insertion. It would have been obvious to one having ordinary skill in the art

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at the time the invention was made to modify the catheter package as taught by Osborne et al with the lubricant and detachable closure as taught by Hursman et al for the purpose of improved operability and ease of insertion.

11. Claims 32 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne et al in view of Swafford (5167646). Osborne et al discloses the invention substantially as claimed except for the closing structure connected to the urinary catheter is provided with a flow channel co-operating with an outlet provided in the package so as, in a first position of the closing structure in relation to the outlet, to prevent a liquid substance to flow from the conduit of the catheter and out of the package. Swafford teaches that it is known to have the closing structure connected to the urinary catheter is provided with a flow channel co-operating with an outlet provided in the package so as, in a first position of the closing structure in relation to the outlet, to prevent a liquid substance to flow from the conduit of the catheter and out of the package (Fig 1, 3) for the purpose of having a closed position wherein no liquid can flow from the nozzle and out of the tube end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the closing structure as taught by Osborne with the closing structure as taught by Swafford for the purpose of having a closed position wherein no liquid can flow from the nozzle and out of the tube end.

Double Patenting

12. Claims 1, 3, 4, 7, 16, 21-23, 26-27, 29, 32-34, 41, 60, 62-64, 67, 68, 70-72 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting

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as being unpatentable over claims 1-20 of copending Application No. 10/482229 and claims 73-75 and 78-88 of copending Application No. 10/183984. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely more broad than the copending cases. Thus the invention claimed in the current application is merely generic to the species in the parent application and it has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571)272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Andrew Gilbert



MICHAEL J. HAYES
PRIMARY EXAMINER